

-17-

We claim:

1. A method of reducing aggregation during dehydration and rehydration of substances comprising the
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adding to a solution or suspension of the substances an amount of trehalose sufficient to prevent aggregation upon rehydration; and

10 dehydrating the solution or suspension.

2. The method according to claim 1 wherein the substances are selected from the group consisting of therapeutic, prophylactic and diagnostic.

15 3. The method according to claim 2 wherein the substances are therapeutic and are biological modifiers.

20 4. The method according to claim 3 wherein the biological modifier is selected from the group consisting of proteins and peptides, steroid hormones, oligosaccharides, nucleic acids and small molecules.

25 5. The method according to claim 4 wherein the proteins are selected from the group consisting of growth hormones, growth factors, insulin, monoclonal antibodies, interleukins and interferons.

30 6. The method according to claim 5 wherein the substance is human growth hormone.

35 7. The method according to claim 4 wherein the steroid hormones are selected from the group consisting of estrogen, progesterone and testosterone.

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-18-

8. The method according to claim 2 wherein the substances are prophylactic substances and are aluminum based adjuvants.

5 9. The method according to claim 8 further comprising the step of incorporating the adjuvants into vaccines.

10 10. The method according to claim 9 wherein the vaccines are diphtheria/tetanus/pertussis (DTP) or inactivated poliovaccine.

15 11. The method according to claim 10 wherein the vaccine is DTP.

20 12. The method according to claim 2 wherein the substance is diagnostic and is selected from the group consisting of colloidal gold, polystyrene latex, fixed erythrocytes and monoclonal antibodies.

25 13. The method according to claim 12 wherein the substance is red blood cells, further comprising the step of fixing the red blood cells prior to adding trehalose.

14. The method according to claim 13 wherein the fixing is by glutaraldehyde.

30 15. The method according to claim 1 wherein the trehalose is added in an amount to obtain a final concentration of from about 1% to 50% (w/v).

35 16. The method according to claim 1 wherein the trehalose is added in an amount to obtain a final concentration of from about 5% to 25% (w/v).

FOI b7D SECE 860

-19-

17. The method according to claim 1 wherein the dehydration step occurs by lyophilization, drying at ambient conditions or drying under reduced vapor pressure.

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18. The method according to claim 17 wherein the drying at reduced vapor pressure occurs at room temperature or at a temperature elevated above room temperature but below a temperature at which degradation or chemical change of the substance occurs.

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19. The method according to claim 1 further comprising the step of rehydrating the substance to obtain a solution or suspension of substantially nonaggregated substance.

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20. A method of reducing aggregation of substances in solution or suspension during freezing comprising the steps of:

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adding to the solution or suspension of the substance an amount of trehalose sufficient to prevent aggregation during freezing; and
freezing the solution or suspension.

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21. The method according to claim 18 wherein the substances are selected from the group consisting of therapeutic, prophylactic and diagnostic.

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22. The method according to claim 21 wherein the substance is therapeutic and is a biological response modifier.

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23. The method according to claim 22 wherein the biological modifier is selected from the group

FOOTNOTES 041601

-20-

consisting of proteins and peptides, steroid hormones, oligosaccharides, nucleic acids and small molecules.

24. The method according to claim 23 wherein
5 the proteins are selected from the group consisting of growth hormones, growth factors, insulin, monoclonal antibodies, interleukins and interferons.

25. The method according to claim 24 wherein
10 the substance is human growth hormone.

26. The method according to claim 23 wherein
the steroid hormones are selected from the group
consisting of estrogen, progesterone and testosterone.
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27. The method according to claim 21 wherein
the substances are prophylactic substances and are
aluminum based adjuvants.

28. The method according to claim 27 further
20 comprising the step of incorporating the adjuvants into vaccines.

29. The method according to claim 28 wherein
25 the vaccines are diphtheria/tetanus/pertussis (DTP) or diphtheria/tetanus/pertussis/inactivated poliovaccine (DTP/IPV).

30. The method according to claim 29 wherein
30 the vaccine is DTP/IPV.

31. The method according to claim 20 wherein
the substance is diagnostic and is selected from the
group consisting of colloidal gold, polystyrene latex,
35 fixed erythrocytes and monoclonal antibodies.

FOI b7D 5299860

-21-

32. The method according to claim 20 wherein the trehalose is added in an amount to attain of from about 1% to 50% (w/v).

5 33. The method according to claim 32 wherein the trehalose is added in an amount to attain of from about 5% to 25% (w/v)

10 34. The method according to claim 20 further comprising the step of thawing the solution or suspension to obtain a solution or suspension of substantially nonaggregated substance.

15 35. An aqueous composition comprising a substance and an amount of trehalose sufficient to prevent substantial aggregation of the substance upon freezing and thawing or dehydrating and rehydrating.

20 36. A frozen composition comprising a substance and an amount of trehalose sufficient to prevent substantial aggregation of the substance upon thawing.

25 37. A dehydrated composition comprising a substance and an amount of trehalose sufficient to prevent aggregation of the substance upon rehydration.

30 38. A composition obtained by the method according to claim 1.

39. A composition obtained by the method according to claim 13.

35 40. A composition obtained by the method according to claim 19.

FOI b7D 5299E860

-22-

41. A composition obtained by the method
according to claim 20.

42. A composition obtained by the method
5 according to claim 34.

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FOOTNOTES